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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

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| IN RE PFIZER INC. SECURITIES LITIGATION | : | 04 Civ. 9866 (RO)<br>(Electronically Filed) |

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO STRIKE CERTAIN EXHIBITS ATTACHED TO THE DECLARATION OF GREGORY A. MARKEL AND RELATED PORTIONS OF THE MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

# TABLE OF CONTENTS

## TABLE OF AUTHORITIES

### CASES

**RULES/STATUTES**

Plaintiffs[1] submit this memorandum of law in support of their motion to strike certain exhibits from the Declaration of Gregory A. Markel (the "Markel Declaration"), as well as associated portions of Defendants' Memorandum of Law in Support of their Motion to Dismiss (the "Motion to Dismiss"),[2] because such documents and associated arguments are outside the proper scope of a motion to dismiss.

## INTRODUCTION

In a premature attempt to raise purported, fact-based defenses to the merits of Plaintiffs' claims, Defendants[3] submitted in support of their Rule 12(b)(6) motion more than forty documents, numbering almost seventeen hundred pages, that are extraneous to the Complaint[4] and one of which has never been made public (the "Disputed Exhibits"). Defendants improperly put forth the Disputed Exhibits in an attempt to dispute and/or mitigate their numerous material misrepresentations about the cardiovascular problems caused by Celebrex and Bextra. None of these documents are quoted, or even referenced, in the Complaint, nor are any of these extraneous documents integral to Plaintiffs' claims. Defendants' effort to have the Court consider documents entirely outside the Complaint clearly violates well-settled principles governing the proper scope of a Rule 12(b)(6) motion to dismiss.

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[1] Lead Plaintiff The Teachers' Retirement System of Louisiana ("Lead Plaintiff") filed the Consolidated Class Action Complaint (the "Complaint") on behalf of all persons and entities who purchased or otherwise acquired Pfizer Inc. ("Pfizer" or the "Company") securities between and including October 31, 2000 through October 19, 2005 (the "Class Period"). Lead Plaintiff, other named plaintiffs, and the class are collectively referred to as "Plaintiffs"

[2] Citation to Defendants' Memorandum of Law in Support of their Motion to Dismiss are designated as "Def. MTD at __"

[3] The defendants in this case are Pfizer and certain of its officers, including Henry A. McKinnell, John L. LaMattina, Karen L. Katen, Joseph M. Feczko and Gail Cawkwell (the "Individual Defendants"). Pfizer and the Individual Defendants are collectively referred to as "Defendants."

[4] Citations to the Complaint are designated as "¶ ____"

Without regard to the merits (or lack thereof) of Defendants' arguments, the Court should completely disregard the Disputed Exhibits at this early stage of the litigation. The actual impact of the Disputed Exhibits and their significance regarding Defendants' fraudulent scheme of misrepresenting and omitting the serious cardiovascular risks associated with Celebrex and Bextra presents factual issues not appropriate for resolution on a motion to dismiss and thus (along with associated portions of Defendants' motion to dismiss) should be stricken. *See Official Comm. of Unsecured Creditors of Color Tile, Inc. v. Coopers & Lybrand, LLP*, 322 F.3d 147, 158 (2d Cir. 2003) ("A court's task in ruling on a Rule 12(b)(6) motion is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof.") (quoting *Ryder Energy Distrib. Corp. v. Merrill Lynch Commodities Inc.*, 748 F.2d 774, 779 (2d Cir. 1984)) (internal quotation omitted). Under clearly established legal principles, the Court may not consider the Disputed Exhibits unless Defendants' Motion to Dismiss is treated as a motion for summary judgment and is disposed of as such – *i.e.*, Plaintiffs are first given the opportunity to conduct discovery and present their own documents and other evidence relevant to the issue of whether Defendants made any actionable misrepresentations or omissions regarding the safety of Celebrex or Bextra. *See Chambers v Time Warner, Inc.*, 282 F.3d 147, 154 (2d Cir. 2002); Fed. R. Civ. P. 12(b).

Unbeknownst to the public (including doctors, patients and investors), Defendants were well aware of the serious (and in some cases deadly) cardiovascular risks associated with Celebrex and Bextra. Defendants failed to publicly disclose the results of a study that found that patients taking Celebrex to treat mild Alzheimer's disease suffered a "statistically significant" increase in heart attacks and other cardiovascular events. Defendants also intentionally distorted the results of a second Celebrex study. Defendants played up that the 6-months of the study

showed an improved gastrointestinal safety profile, but intentionally failed to tell the public that the study actually encompassed a 12-month period. In that full 12-month period, the study's participants experienced serious cardiovascular problems, including elevated rates of anginal disorders, myocardial infarction and heart attacks. The same was true for Bextra. Defendants withheld material data that patients taking Bextra who underwent Coronary Artery Bypass Graft ("CABG") Surgery experienced excessive cardiovascular thromboembolic events.

Markel Exhibit 1, which relates solely to Plaintiffs' Bextra-related claims, attaches excerpts of "confidential" portions of Defendants' Bextra approval package, including excerpts from a 4,326 page "Final Report for the Evaluation of the Safety and Efficacy of Parecoxib 40 MG Q 12H Followed By Valdecoxib 40 MG Q 12H in Patients Who Have Coronary Artery Bypass Graft via Median Sternotomy,"[5] dated August 25, 2000, (the "Final Report"). This Final Report states:

Parecoxib Sodium
Parecoxib/Valdecoxib Safety vs
Placebo Following CABG

| Incidence of ALL CRAEs | | | |
|---|---|---|---|
| **CRAE** | | placebo N=151 n (%) | Parecoxib/valdecoxib 40 mg Q 12h N=311 n (%) |
| **Any CRAE** | IV dosing | 14 (9 3) | 36 (11 6) |
| | entire study | **23 (15.2)** | **80 (25.7)†** |
| **Death** | IV dosing | 0 (0) | 2 (0 6) |
| | entire study | 0 (0) | 4 (1.3) |
| **CVA** | IV dosing | 0 (0) | 5 (1 6) |
| | entire study | 1 (0.7) | 9 (2.9) |
| **DVT** | IV dosing | 0 (0) | 0 (0) |
| | entire study | 0 (0) | 3 (1.0) |
| **Pulmonary embolism** | IV dosing | 0 (0) | 1 (0 3) |
| | entire study | 0 (0) | 2 (0.6) |
| **Congestive heart failure** | IV dosing | 0 (0) | 0 (0) |
| | entire study | 1 (0.7) | 4 (1.3) |
| **Pericarditis** | IV dosing | 0 (0) | 2 (0 6) |
| | entire study | 1 (0.7) | 4 (1.3) |
| * * * | | | |
| † - **statistically significant difference between treatment groups at $p < 0.05$.** | | | |
| Considering only major CRAE's, defined as (1) death; (2) all cardiovascular events; (3) all GI events; (4) infections that | | | |

[5] Parecoxib is an injectable version of Valdecoxib (Bextra).

required re-operation or parenteral antibiotics and all cases of sepsis; and (5) renal events associated with a serum creatinine value >2 0 mg/dL and increase of >0 7 mg/dL relative to Baseline. a statistically significant higher overall rate of major CRAEs was noted during the entire study for parecoxib/valdecoxib than for placebo

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The higher overall event rates for a major CRAE with parecoxib/valdecoxib were primarily driven by the higher rates of death, CVA, GI events. and infection Of the 10 patients with a major CVA. two were less than 65 years of age and eight were at least 65 years age Logistic regression analysis of potential risk factors for major CVA revealed that prior CVD, age ≥ 65 years, and BMI ≥ 30 were associated with an increased risk of a major CVA event with parecoxib/valdecoxib; the same risk factors, in the same order of relative significance, were identified for all patients

Markel Decl. Ex. 1; Excerpts from chart on page 6 of 4326 (emphasis added). This Final Report shows that Defendants were aware of the statistically significant cardiovascular risks associated with Bextra. It states 25.7% (80 out of 311) patients administered parecoxib/valdecoxib, *i.e.*, Bextra, suffered clinically relevant adverse events ("CRAE") versus 15.2% (23 out of 151) patients administered placebo, ***nearly double***. *See* Markel Decl. Ex. 1 at p. 6 of 4,326 and p. 14 of 4,326. The clinically relevant adverse events included death, myocardial infarction, cerebral vascular accidents ("CVA"), deep vein thrombosis ("DVT"), pulmonary embolism, congestive heart failure, pericarditis, renal failure/dysfunction, GI event, major non-GI bleed, infection, pulmonary complication. Defendants admit in the Final Report that this 10.5% difference (25.7% versus 15.2%) is a "***statistically significant*** difference between treatment groups at p <0.05[%]." *See id.* at p. 6 of 4,326 (emphasis added). Of course, and itself illustrative of Defendants' scienter, by dividing the CRAE into enough sub-categories, Defendants claimed that no individual sub-category of adverse cardiovascular event was statistically significant. *Id.*

Thus, Defendants admit their knowledge of Bextra's problems. Those same risks resulted in Bextra being removed from the market on April 7, 2005. Nonetheless, even though the proffered documents support Plaintiffs, their use is improper. Defendants' reliance on extraneous documents is an admission of the sufficiency of the allegations in the Complaint and simply confirms the highly factual nature of Defendants' putative defenses. Under settled legal

principles the extraneous exhibits should be stricken along with the related sections of Defendants' memorandum of law.

## FACTUAL BACKGROUND

### A. The Complaint

On February 16, 2006, Plaintiffs filed the Complaint against Defendants. The Complaint alleges that throughout the Class Period Defendants misrepresented critical information regarding Celebrex and Bextra, two of Pfizer's painkillers that are part of a class of drugs known as COX-2 inhibitors. Specifically, Pfizer claimed that these drugs did not cause adverse cardiovascular effects and caused fewer gastrointestinal side effects than other types of painkillers. ¶¶ 55-106. As a result of Pfizer's misrepresentations, Celebrex became the most successful new drug launch in history and, together with Bextra, became two of the most successful drugs in the world, with annual sales exceeding $4.5 billion per year in 2004. ¶¶ 69, 71. As a result of these sales, which were based upon lies about the alleged safety and superiority of the drugs, Pfizer's stock price was artificially inflated by tens of billions of dollars.

Unbeknownst to investors (and users of these drugs), Pfizer possessed data reflecting serious cardiovascular risks associated with Celebrex and Bextra, contradicting or rendering false Defendants' statements throughout the Class Period about the alleged safety of those drugs. ¶ 2. Defendants, for example, failed to disseminate to the public results from a study ending in 1999, that found patients taking Celebrex to treat mild Alzheimer's disease had a statistically significant increase in heart attacks and other cardiovascular side effects (the "1999 Study").

¶¶ 4, 91-97.[6] Defendants also skewed the results of a second study linking Celebrex use to cardiovascular risk, the Celecoxib Long-Term Arthritis Safety Study (the "CLASS"), by playing up the first 6-months results to support a claim of improved gastrointestinal safety for Celebrex, without disclosing that the entire 12-month study revealed that Celebrex posed serious cardiovascular problems. ¶¶ 101-105.

After hiding the 1999 Study for nearly five years and skewing the results of the CLASS, and only after the National Cancer Institute halted a Celebrex trial in December 2004 because of increased adverse cardiovascular events, Pfizer finally, in January 2005, made available to the public the results of the 1999 Study. ¶¶ 6, 97. As a result of the tardy revelation of the 1999 Study and the problems with the CLASS, as well as other information, the Food and Drug Administration ("FDA") required Celebrex to carry a "black-box" warning highlighting the potential for increased risk of cardiovascular events and gastrointestinal bleeding associated with Celebrex use. ¶¶ 137- 47. The "black box" warning is the most serious warning placed in the labeling of prescription medication and is used by the FDA for special problems, particularly those that may lead to death or serious injury.

Defendants knew, from its initial approval, that Celebrex should have always carried the "black box" FDA warning it now carries warning of the substantial risk of cardiovascular harm that Celebrex can cause. ¶ 3. Had Celebrex's label always carried this "black-box" warning, Celebrex would have been nothing more than a niche painkiller used by a segment of special-need patients rather than the "blockbuster" it became. ¶ 3.

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[6] The Complaint alleges that "Pfizer's own analysis" of the 1999 Study found "***statistically significant***" the 4 to 1 difference between patients taking Celebrex who suffered heart attacks versus those taking a placebo. ¶ 135 (emphasis added) *See also* ¶ 4, 41, 94, 303 (the authors of the 1999 Study wrote: "A ***statistically significant*** difference favoring placebo in adverse events was observed.") (emphasis added)

As they did with Celebrex, Defendants also withheld from investors, doctors, and patients critical information about Bextra. In particular, Pfizer withheld from the public information concerning the Coronary Artery Bypass Graft Trial ("CABG Trial 35"). Although information about this study, which showed serious cardiovascular problems associated with Bextra use, was provided to the FDA, the cardiovascular safety information in the FDA approval package for Bextra was redacted from the versions of these documents Pfizer made available to the public. ¶¶ 106-112. This is of material importance because the unredacted version of the Bextra approval package contains a cautionary statement from the FDA noting an excess of serious cardiovascular thromboembolic events reported in CABG Trial 35. ¶ 111. Ultimately, the FDA caused Bextra to be removed from the market.

The "black-box" warning label on Celebrex and the withdrawal of Bextra from the market had a huge impact on Pfizer's revenues and earnings. Combined, Celebrex and Bextra's revenues for the first nine months of 2005 fell by over $2 billion compared to the first nine months of 2004, a decline of 63%. ¶ 9. As a result, Pfizer's common stock price fell dramatically. From October 18, 2004 to the end of the Class Period, Pfizer's stock experienced a series of drops, falling from $29.00 per share on October 18, 2004 to $21.90 per share on October 20, 2005, representing a loss in market capitalization of $50 billion. ¶¶ 9, 83, 150.

Plaintiffs bring this action on behalf of Pfizer's investors to recover damages sustained in connection with the decline in Pfizer's stock price that resulted from the public disclosure of Defendants' fraudulent material misrepresentations and omissions about the safety of Celebrex and Bextra.

**B. Defendants' Motion to Dismiss**

On May 5, 2006, Defendants moved to dismiss the Complaint pursuant to Rule 12(b)(6), and simultaneously filed more than forty exhibits appended to the Markel Declaration in support

thereof. Defendants erroneously argue, in part, that Plaintiffs' Section 10(b) claim must fail because Plaintiffs do not allege that Defendants made any actionable misrepresentations or omissions and that Plaintiffs failed to adequately plead that Defendants acted with scienter. Def. MTD at 13-30, 31-52. Defendants are wrong. As Plaintiffs demonstrate more fully in their opposition to the Motion to Dismiss, the Complaint alleges actionable misrepresentations and omissions as well as Defendants' scienter concerning, *inter alia*: (1) Celebrex in connection with Defendants' intentional failure to disclose the adverse cardiovascular results of the 1999 Study, and in connection with Defendants' distortions of the CLASS (*see, e.g.*, ¶¶ 31-36, 94-95, 284); and (2) Bextra in connection with Defendants' intentional failure to disclose the adverse cardiovascular results of CABG Trial 35. *See, e.g.*, ¶¶ 110-112, 118.

Apparently recognizing that their legal arguments lack merit, Defendants raise a number of factual issues that purportedly contradict allegations in the Complaint. They seek to support these factual arguments by attaching to the Markel Declaration, and relying upon in their Motion to Dismiss, a number of self-serving documents that are wholly outside the Complaint. One of the Disputed Exhibits ("Markel Exhibit 1") has never even been made public and is deemed so sensitive that Defendants filed this exhibit and related portions of their motion "under seal." The Disputed Exhibits include exhibit numbers 1, 1a, 2 and 3 appended to the Markel Declaration.

Markel Exhibit 1 includes, *inter alia*, a confidential draft label for Bextra and excerpts from a confidential "Final Report." *See supra* at pgs 3-4. It was impossible for Plaintiffs to have included or relied upon this previously undisclosed document in the portion of the Complaint that relates to Defendants' Bextra-related misrepresentations and omissions.

Markel Exhibit 1a comprises an anonymous "Primer" from the American College of Physicians entitled "Statistical Significance and *P* Values." However, this "Primer" is not incorporated in the Complaint in any way, and it was not relied upon by Plaintiffs in bringing suit. Markel Exhibits 2 and 3, both of which purport to relate to both Bextra and Celebrex, are a tiny fraction of materials available concerning the prevalence and types of arthritis. Markel Exhibits 2 and 3 are irrelevant to Plaintiffs' claims and were not mentioned in the Complaint. The Disputed Exhibits are not "official public documents" (such as SEC filings), were neither mentioned in nor incorporated into the Complaint, were not in Plaintiffs' possession, and are not documents upon which Plaintiffs relied in bringing this case.

## ARGUMENT

### I. LEGAL STANDARD APPLICABLE TO STRIKING FROM A MOTION TO DISMISS MATERIAL THAT IS OUTSIDE A COMPLAINT

On a motion to dismiss under Rule 12(b)(6), a district court is required to view all allegations raised in the complaint in the light most favorable to the non-moving party, *Newman & Schwartz v. Asplundh Tree Expert Co.*, 102 F.3d 660, 662 (2d Cir. 1996); *Cosmas v. Hassett*, 886 F.2d 8, 11 (2d Cir. 1989), and "must accept as true all the factual allegations in the complaint." *Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit*, 507 U.S. 163, 164 (1993). Thus, "[i]n considering a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a district court must limit itself to facts stated in the complaint or in documents attached to the complaint as exhibits or incorporated in the complaint by reference." *Kramer v. Time Warner Inc.*, 937 F.2d 767, 773 (2d Cir. 1991); *Cosmas*, 886 F.2d at 13 (providing that a district court should limit itself to a consideration of the factual allegations made in the complaint in deciding a motion to dismiss). These requirements are strictly enforced. *See Amaker v. Weiner*, 179 F.3d 48, 50 (2d Cir. 1999) (stating that the Second Circuit

will "strictly enforce the conversion requirement of Rule 12(b) where there is a legitimate possibility that the district court relied on inappropriate material in granting the motion").[7] Further, the Court clearly has the power to strike documents and arguments that are outside the scope of the pleading. *See In re OPUS360 Corp. Sec. Litig.*, No. 01 Civ. 2938, 2002 WL 31190157, at *1 n.3 (S.D.N.Y. Oct. 2, 2002) (granting the plaintiffs' motion to strike exhibits on a motion to dismiss); *In re Cree, Inc. Sec. Litig.*, 333 F. Supp. 2d 461, 470-71 (M.D.N.C. 2004) (granting the plaintiffs' motion to strike and refusing to take judicial notice of articles submitted by the defendants in support of their motion to dismiss).

When "matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Fed. R. Civ. P. 12(b). *See also Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991) ("We suggested nearly 50 years ago that such motions be treated as motions for summary judgment and disposed of as such"). Under such circumstances, the non-moving party must be given an opportunity to meet its burden of proof after discovery. *See Chambers*, 282 F.3d at 154 ("Once the District Court was presented with matters outside the pleadings, . . . [t]he court could have excluded the extrinsic documents . . . [or] the court [is] obligated to convert the motion to one for summary judgment and give the parties an opportunity

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[7] *See also Friedl v. City of New York*, 210 F.3d 79, 83 (2d Cir. 2000) ("When matters outside the pleadings are presented in response to a 12(b)(6) motion: the court may exclude the additional material and decide the motion on the complaint alone or it may convert the motion to one for summary judgment under Fed. R. Civ. P. 56 and afford all parties the opportunity to present supporting material") (internal quotations and citations omitted); *Kopec v. Coughlin*, 922 F.2d 152, 154-55 (2d Cir. 1991) (reversing a Rule 12(b)(6) dismissal where the district court did not convert the motion to one for summary judgment but nonetheless relied on extrinsic materials attached to the motion to dismiss).

to conduct appropriate discovery and submit the additional supporting materials contemplated by Rule 56").

A court may consider documents extraneous to the complaint without converting the motion to dismiss into one for summary judgment only in the very limited circumstances "where the complaint 'relies heavily upon its terms and effect,' which renders the document 'integral' to the complaint." *Id.*; *See also Cortec Indus.*, 949 F.2d at 48 (providing that a district court may consider on a motion to dismiss "documents plaintiffs had either in its possession or had knowledge of and upon which they relied in bringing suit"); *In re Independent Energy Holdings PLC Sec. Litig.*, 154 F. Supp. 2d. 741, 748 (S.D.N.Y. 2001) (quoting *Rothman v. Gregor*, 220 F.3d 81, 88 (2d Cir. 2000)) (same).

In addition, in deciding a motion to dismiss on a complaint alleging securities fraud, a district court may take judicial notice to "review and consider pubic disclosure documents required by law to be and which actually have been filed with the SEC."[8] *Cortec Indus.*, 949 F.2d at 47. However, even if a court considers documents that are extraneous to the complaint, the court may only determine whether those documents exist and contain certain assertions. *Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1277 (11th Cir. 1999) (adopting the Second Circuit's reasoning in *Kramer* and permitting the court to take judicial notice of relevant documents legally required by and publicly filed with the SEC for the limited purpose of

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[8] The court may take judicial notice of facts that are "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. *See also Brass v. American Film Tech., Inc.*, 987 F.2d 142, 150 (2d Cir. 1993) ("When determining the sufficiency of plaintiffs' claim for Rule 12(b)(6) purposes," a district court may consider "documents . . . to matters of which judicial notice may be taken") Courts typically take judicial notice of official public records and well-publicized public records. *See, e.g., Thomas v. Westchester County Health Care Corp.*, 232 F. Supp. 2d 273, 276 (S.D.N.Y. 2002) (holding that "the Court 'may take judicial notice of the records of state administrative procedures . . .'"); *Ganino v. Citizens Util. Co.*, 228 F.3d 154, 167 n.8 (2d Cir. 2000) ("the district court may take judicial notice of well-publicized stock prices")

determining what statements the documents contain and not to prove the truth of the documents' contents). The court may not rule on the truth or falsity of matters contained in the documents. *Kramer* 937 F.2d at 774 (noting that in "considering such documents when faced with a motion to dismiss a securities action based on allegations of material misrepresentations or omissions ... the documents ... are relevant not to prove the truth of their contents but only to determine what the documents stated.").[9]

In *Chambers*, the Second Circuit held that the district court improperly considered certain collective bargaining codes of fair practice in dismissing the plaintiffs' copyright and Lanham Act claims. *Chambers*, 282 F.3d at 154. Because the amended complaint did not refer to the codes and the plaintiffs did not rely on the codes in drafting their amended complaint, the Second Circuit reasoned that the codes were not integral to the amended complaint and should not have been considered by the district court. *Id*

Here, Defendants have improperly submitted and relied upon the Disputed Exhibits in connection with their Motion to Dismiss. These documents are not official public records (such as SEC filings) and are not cited in or integral to the Complaint. Moreover, Defendants improperly seek to use the Disputed Exhibits to prove what they claim is the truth of the matters contained in those documents. In fact, as explained below (*see infra* Section II), Defendants' "truth" is nothing more than a strained interpretation of those documents and the actual meaning of those documents cannot be ascertained without full discovery. Thus, a motion to strike is the proper remedy.

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[9] *See also Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996) (adopting the Second Circuit's rule from *Kramer*, the Court held that when deciding a motion to dismiss a securities action, documents required to be filed and actually filed with the SEC should be considered "only for the purpose of determining what statements the documents contain, not to prove the truth of the documents' contents").

## II. THE DISPUTED EXHIBITS MAY NOT PROPERLY BE CONSIDERED ON A MOTION TO DISMISS

Defendants argue that the Court may take judicial notice of documents referenced or quoted in the Complaint, integral to Plaintiffs' claims, in Plaintiffs' possession, or of which Plaintiffs had knowledge and relied upon in bringing suit. Def. MTD at 2 n.3, 8 n.11. However, none of the Disputed Exhibits were referenced or quoted in the Complaint, integral to Plaintiffs' claims, in Plaintiffs' possession, or within Plaintiffs' knowledge and relied upon by Plaintiffs in bringing suit. Defendants erroneously make a blanket assertion that all of the exhibits contained in the Markel Declaration fall within one of these categories.

First, Markel Exhibit 1, which purports to relate to only the Bextra-related claims, consists of excerpts from *confidential* Bextra approval materials allegedly submitted to the FDA that have never been available to the public, are subject to a protective order in another litigation, and have been filed under seal in this case. Thus, it was impossible for Plaintiffs to have included or relied upon Markel Exhibit 1 in the Complaint. Further, Markel Exhibit 1 contains only miniscule *excerpts* of thousands of confidential Bextra-related documents allegedly submitted to the FDA. For the Court to take judicial notice of this incomplete record would be fundamentally unfair, because it would preclude Plaintiffs from reviewing the totality of the documents. *See Chambers*, 282 F.3d at 155 ("when a district court considers certain extra-pleading materials and excludes others, it risks depriving the parties of a fair adjudication of the claims by examining an incomplete record."). *See generally* Fed. R. Evid. 106 (when one party introduces only part of a document, other parts of the document should be introduced "which ought in fairness to be considered contemporaneously").[10]

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[10] Markel Exhibit 1 shows that Defendants were aware of the statistically significant cardiovascular risks associated with Bextra. It states 80 out of 311 patients administered parecoxib/valdecoxib, i.e. Bextra or 25.7% of patients

Second, the Court should not take judicial notice of Markel Exhibit 1a (purporting to relate to both Bextra and Celebrex claims) -- an anonymous "Primer" from the American College of Physicians entitled "Statistical Significance and *P* Values," which Defendants use to suggest that "[i]f there is a less than 5% probability that the observed result [of a study] is due to chance . . . researchers typically assert that the findings are 'statistically significant.'" Def. MTD at 2 n.1. This document should be stricken because it was not incorporated in the Complaint nor was it relied upon by Plaintiffs in bringing suit. Additionally, accepting the 5% threshold proposed by Defendants for determining "statistically significant" evidence raises a factual issue not appropriate for a motion to dismiss. The issues raised in this "Primer" are complex and subject to differing views – precisely the types of issues to be addressed in a highly fact-sensitive "battle of the experts." The "Primer" even acknowledges this factual dispute, stating that the 5% threshold "is wholly arbitrary" and "could just as easily be 10% or 1%." Markel Decl. Ex. 1a, at 3.

Third, the Court should not take judicial notice of Markel Exhibits 2 and 3 (purporting to relate to both Bextra and Celebrex claims), which comprise web-based pages from the National Center for Chronic Disease and Health Promotion. Defendants use these exhibits to highlight the prevalence of arthritis in the United States, as well as to explain the different types of arthritis (osteoarthritis and rheumatoid arthritis). Def. MTD. at 3 n.4. These exhibits are irrelevant to Plaintiffs' securities fraud claims. More importantly, they should be stricken because they are outside the factual allegations made in the Complaint or any document incorporated in the Complaint by reference.

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suffered clinically relevant adverse events ("CRAE") versus 23 out of 151 patients administered placebo (15.2%). *See* p. 6 of 4326 and p. 14 of 4326. The Final Report states this 25.7% versus 15.2% difference is a "***statistically significant*** difference between treatment groups at p <0.05[%]." *See* p. 6 of 4,326

There also is no basis for this Court to take "judicial notice" of these exhibits.[11] The Disputed Exhibits are not "official," public records of a governmental agency.[12] Nor are they matters of general public knowledge that is not subject to dispute.[13]

Here, as in *Chambers*, none of the Disputed Exhibits were referenced in or integral to the Complaint. In addition, Plaintiffs have not had an opportunity in discovery to examine the authenticity, completeness, origin and/or accuracy of, or the circumstances giving rise to, the Disputed Exhibits. *See Adams v. Crystal City Mariott Hotel*, No. 02 Civ. 10258, 2004 WL 744489, at *3 (S.D.N.Y. Apr. 6, 2004) (declining to consider a Certification submitted by the plaintiff in response to the defendant's motion to dismiss where the plaintiffs "did not attach the Certification to the Pleadings, nor did she incorporate the Certification to the pleadings by reference"); *SEC v. Downe*, No. 92 Civ. 4092, 1993 WL 22126, at *14 n.3 (S.D.N.Y. Jan. 26, 1993) (refusing to consider "factual assertions [made by the defendants] concerning matters outside the complaint" because "[r]eliance on these extraneous materials by the Court is

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[11] Plaintiffs have not objected to Pfizer's public filings with the SEC attached to the Markel Declaration. In *Kramer*, the Second Circuit held that the district court properly considered on a motion to dismiss an Offer to Purchase and Joint Proxy Statement, because those documents were required to be and were actually filed, publicly, with the SEC. *Kramer*, 937 F.2d at 774. As explained above, the Disputed Exhibits do not consist of documents required by law to be filed with the SEC.

[12] Courts have defined as matters of public record, for purposes of what may be considered in a Rule 12(b)(6) motion, things such as statutes, case law, city charters, city ordinances, criminal case dispositions, letter decisions of government agencies, published reports, records of administrative agencies, or pleadings in another action. *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 128 (E.D.N.Y. 2003) (stating "the Court may consider matters of public record, such as court decisions, statutes, and documents such as briefs filed with courts and other public bodies") (citing *Papasan v. Allain*, 478 U.S. 265, 268, 269 n.1 (1986)); *Evans v. New York Botanical Garden*, No. 02 Civ. 3591, 2002 WL 31002814, at *4 (S.D.N.Y. Sept. 4, 2002) (taking judicial notice of state administrative procedures); *Dutton v. Swissport USA, Inc.*, No. 04 CV 3417, 2005 WL 1593969, at *1 (E.D.N.Y. July 1, 2005) (taking judicial notice of a transcript from Worker's Compensation Board hearing and the plaintiff's worker's compensation complaint).

[13] *See In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 402 F. Supp. 2d 434, 437 n.15 (S.D.N.Y.), *aff'd*, 429 F.3d 370 (2d Cir. 2005) (taking judicial notice of California state court opinions and orders, and legislative history of California Civil Code attached to motion to dismiss because documents were not in dispute); *Fridman v. City of New York*, 183 F. Supp. 2d 642, 655 (S.D.N.Y.), *aff'd*, 52 Fed. Appx. 157 (2d Cir. 2002) (taking judicial notice of state court opinion because the "text and existence of the State Opinions is not in dispute and are capable of ready and accurate determination").

improper on a motion to dismiss" and providing that "[w]hile the Court has the power to convert this motion into one for summary judgment, ... the Court expressly declines to do so"). This is not a case where Plaintiffs chose "not to attach to the complaint or incorporate by reference a [document] upon which [they] solely rel[y] and which is integral to the [C]omplaint." *Cortec Indus.*, 949 F.2d at 47.

None of the cases cited by Defendants support their argument that the Court should take judicial notice of the Disputed Exhibits. The cases cited by Defendants in support of their position that the Court may take judicial notice of the Disputed Exhibits are: (1) *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182 (11th Cir. 2002); (2) *Kramer*, 937 F.2d at 767; (3) *In re Wellbutrin Sr/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751 (E.D. Pa. 2003); and (4) *Chan v. Orthologic Corp.*, No. Civ. 96-1514, 1998 WL 1018624 (D. Ariz. Feb. 5, 1998). *See* Def. MTD at 2 n.3.

The Eleventh Circuit's holding in *Oxford Asset Mgmt.* is misconstrued by Defendants. The documents at issue there – a prospectus, a Form 10-Q, an analyst report, an article and press releases – were either quoted in the complaint[14] or were required to be filed with the SEC and were actually so filed. *Oxford Asset Mgmt.*, 297 F.3d at 1188 (stating that when a court considers SEC filings, the documents "may only be considered to show their contents, not to prove the truth of the matters asserted therein"). The court in *Oxford Asset Mgmt.* further found that the district court appropriately took judicial notice of the remaining document – a package insert for the pharmaceutical drug Niaspan – because it was included in every package of Niaspan, it was listed in the Physician's Desk Reference, and it was part of the FDA's *public* file.

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[14] *See also Harris v. Ivax Corp.*, 182 F.3d 799, 802 n.2 (11th Cir. 1999) (permitting courts to consider documents central or attached to the complaint in order to view "allegedly fraudulent statement in its context.").

Not only was the insert publicly available, the lower court merely used the insert to show the bare existence of a clinical study, not to establish the results of the study. *Id.* at 1188 (finding no error in the lower court taking judicial notice of the contents of the package insert because the lower court did not accept the facts asserted in the insert as true). But the *Oxford Asset Mgmt.* court specifically held that the FDA file could be judicially noticed not for the truth of the assertions therein but only for its existence. *Id.*

*Oxford Asset Mgmt.* is wholly inapposite here because the *confidential* excerpts of the draft Bextra approval package submitted as Markel Exhibit 1 were not included in the Complaint and were never part of the FDA's *public* file, nor were they ever made available to the public. Also in contrast to *Oxford Asset Mgmt.*, Defendants seek to prove more than the "bare existence" of the Disputed Exhibits and to prove the truth of the facts asserted in those documents. *Id.*

The *Wellbutrin* and *Chan* decisions also are inapposite because they dealt solely with "official" documents that were part of the FDA's *public* records. *See Wellbutrin,* 281 F. Supp. 2d at 754 n.2 (deciding to take judicial notice of a FDA report because it was a public record published on the FDA's official website); *Chan,* 1998 WL 1018624, at *5 (finding judicial notice proper for an FDA initial approval order because it was matter of public record). In *Chan*, the court took judicial notice of an FDA approval order, reasoning that the document was a matter of public record and that the parties did not dispute the existence of the document. *Chan*, 1998 WL 1018624, at *5. However, the court declined to take judicial notice of various communications between the company and the FDA. *Id.* at *6. In doing so, the court reasoned that "it is ... undesirable to turn every motion to dismiss into a pseudo-summary judgment motion without invoking the normal consequences." *Id.* at *7. Moreover, in neither case did the court refer to the content of the judicially-noticed documents and, therefore, could not possibly have been

using these documents for the truth of their content. *Wellbutrin*, 281 F. Supp. 2d at 756-757; *Chan*, 1998 WL 1018624, at *7.

Here, as noted previously, Markel Exhibit 1 was not part of the public record and these decisions are not applicable. Moreover, Defendants improperly seek to use the Disputed Exhibits to prove the truth of those documents' contents. Defendants rely upon Markel Exhibit 1 to argue that the number of heart attacks and strokes that Bextra users suffered during clinical trials were not "statistically significant" and to claim that Pfizer fully disclosed Bextra's known cardiovascular risks. *See* Def. MTD at 9-11. This factual argument is simply impermissible. *See Kramer*, 937 F.2d at 774 (taking judicial notice of SEC public filings "not to prove the truth of their content but only to determine what the document stated.").

Defendants also argue that they were under no duty to disclose the adverse effects associated with Celebrex and Bextra because no "statistically significant" evidence shows that Celebrex and Bextra caused the adverse cardiovascular events. *See* Def. MTD at 2, 4, 33-38, 44-45. Defendants improperly use Markel Exhibit 1a to prove the truth that a study's findings are "statistically significant" where "there is a less than 5% probability that the observed result [of the study] is due to chance . . . ." *Id.* at 2 n.1. However, Defendants blithely ignore allegations in the Complaint that the authors of the 1999 Study found "statistically significant" the high number of patients suffering heart attacks, strokes and other heart problems while taking Celebrex compared to the placebo group. ¶¶ 94, 135.

Defendants also seek to prove the truth of the matters contained in Markel Exhibits 2 and 3, consisting of materials from the National Center for Chronic Disease and Health Promotion that highlighted the prevalence of arthritis in the United States and explained the types of arthritis. Defendants have the hubris to attempt to justify, or at least mitigate, their fraudulent

misrepresentations about the cardiovascular safety of Celebrex and Bextra by citing the prevalence of arthritis in the United States and the economic losses suffered as a result of this incurable disease. *See* Def. MTD at 3. This logical non-sequitur is as puzzling as it is improper under Rule 12(b)(6).

The bottom line is that Defendants failed to disclose to the FDA and the public – including physicians, patients and, most importantly to this case, Pfizer investors – data reflecting the serious cardiovascular risks associated with Celebrex and Bextra. ¶¶ 2, 3, 91-119. Defendants misrepresented Celebrex and Bextra as risk-free painkillers with a wide variety of applications to be taken by a broad group of patients. ¶ 2. Had data known by Pfizer been properly disclosed to the public, Bextra would have never been approved for use by consumers, and Celebrex would have been subject to the "black box" FDA warning it now carries. ¶ 3. Indeed, members of the 1999 Study's safety panel stated that they would have recommended that Celebrex carry a warning about its cardiovascular risks had they known about Celebrex's safety issues. ¶¶ 4, 96. Ultimately, Celebrex and Bextra should have never became two of the most successful drugs in the world, with billions of dollars in annual revenues.

This Court should not consider any of the Disputed Exhibits. Plaintiffs have not objected to the vast majority of 1,678 pages of exhibits that Defendants have attached to their Motion to Dismiss and upon which they rely in seeking dismissal of Plaintiffs' claims, because these exhibits, in large part, consist of Pfizer's public filings with the SEC. The Disputed Exhibits are not "official public records" nor are they referenced in or integral to the Complaint. Consideration of such extraneous documents would convert Defendants' Motion to Dismiss into one for summary judgment. In that event, Plaintiffs would have to be provided with a reasonable opportunity to conduct appropriate discovery. However, discovery is stayed pending the

resolution of Defendants' motion. *See* 15 U.S.C. § 78u-4(b)(3)(B). Accordingly, neither the Disputed Exhibits, nor any reference to such exhibits, should be considered.

## CONCLUSION

For all the foregoing reasons, the Disputed Exhibits should be stricken from the record, and all references to the Disputed Exhibits in Defendants' Motion to Dismiss and supporting brief should be disregarded.

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Respectfully submitted,

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